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TITLE PAGE

Non-pharmacological interventions for reducing aggression and violence in serious mental illness: a systematic review and narrative synthesis

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1. INTRODUCTION

Patients with serious mental illness (SMI) are at higher risk of committing acts of violence than the general population[1,2,3] and are over-represented in the criminal justice setting[4,5,6,7] yet the majority of the violence literature pertains to an offending population without mental disorder. People with personality disorder (PD) have similarly increased violence rates and this increases further if the diagnosis is antisocial PD (ASPD)[8]. Previous reviews have presented evidence supporting the efficacy of pharmacological treatments in reducing violence during psychosis[9, 10] but issues including non-adherence and non-response to anti-psychotic medications[11] and the aetiological heterogeneity of violence during psychosis[12] may limit the efficacy of pharmacological treatments across the spectrum of violent psychiatric patients and mentally disordered offenders (MDOs).

Non-pharmacological interventions to reduce violence are delivered to offenders with and without mental disorder but the literature describing their efficacy in an SMI population is scarce. Such interventions are delivered in both healthcare and criminal justice settings on the assumption that MDOs share dynamic risk factors and procriminal thinking styles with the mentally healthy offender population[13] for whom a broader literature for violence rehabilitation exists.

However, MDOs are not standard prisoners; recidivism rates for violence are less than that of the prison population or those with a primary PD diagnosis[14,15]. Nor are they like general psychiatric patients, who are assumed to be more engaged with treatment, more insightful and less violent in comparison with MDOs. MDOs reside at the interface between the healthcare and criminal justice systems, receiving care in diverse settings including prison, hospitals (secure or general) and the community.

In 2004, Blackburn considered the evidence base for psychological interventions for MDOs in the context of the “What Works” literature for offender rehabilitation[16]. He concluded that there was little robust evidence in this specific population and that which was available was limited to short-term outcomes of routine interventions lacking a controlled experimental design.

A recent systematic review[17] provided tentative support for the utility of Cognitive Behavioural Therapy (CBT) in reducing aggressive behaviour in forensic and psychiatric populations with a history of violent behaviour. This review did not target the SMI population exclusively and its focus on CBT may have excluded other potential non-pharmacological approaches.

1.1 Objectives

This study aims to aggregate all non-pharmacological (psychological, legal and social) interventions for reducing aggression and violence in adults with SMI and to assess the efficacy of these interventions.

Research question

What is the evidence for non-pharmacological interventions in reducing the recurrence of violence (physical violence, verbal aggression, violent attitudes) in people with SMI (specifically affective and non-affective psychosis and/or personality disorder)?

2. METHODS

The review was performed as per the PRISMA guidelines[18].

Prior to commencing the review, we performed an on-line literature search to ensure that a similar review had not been published. The Cochrane Review Database, Centre for Reviews and Dissemination (CRD), Campbell Collaboration Library, MEDLINE, EMBASE, PSYCHINFO, Health Management Information Consortium Database (HMIC), Database of Promoting Health Effectiveness Reviews (DoPHER) and the Evidence Based Policing Matrix were searched with the search string '*psychosis OR psychotic OR schizo* AND offen* OR crim* OR violen* OR assault**'.

No systematic reviews were found which replicate the intention of this study. Previous reviews which have focussed on violence reduction in a mental health population either took a broader approach to included diagnoses and outcomes or focus on mixed/ exclusively pharmacological interventions[19,20,21].

2.1 Protocol and registration

The review protocol was registered with the PROSPERO International Prospective Register of Systematic Reviews on 2/5/2014 and can be accessed via the PROSPERO website at <http://www.crd.york.ac.uk/prospero/>. The PROSPERO registration number for the review is CRD42014009400.

2.2 Eligibility criteria

The review sought to identify papers that evaluated the effect of non-pharmacological interventions on violence outcomes in a population with a specified mental disorder and a history of violence. This would include psychiatric inpatients, outpatients and MDOs in prison. For the purposes of this review, SMI was defined as schizophrenia spectrum disorders, schizoaffective disorder or bipolar disorders. All types of controlled study design were included to increase the number of returns. The search was not limited to any aspect of timing, allowing consideration of the evidence base for the short, medium and long term. The authors searched for papers published between January 1st 1980 and June 1st 2015.

Inclusion criteria were:

- a) Adults (18 and over) with a primary diagnosis of SMI and/or personality disorder with a history of violence or aggression.
- b) Any form of specific non-pharmacological intervention
- c) Violence (physical violence, verbal aggression or violent attitudes) as outcome measure
- d) Published in the English language

Exclusion criteria were:

- a) Patients with intellectual disability
- b) Sexual violence
- c) Emergency management of violence
- d) Uncontrolled case reports or case series

2.3 Study selection

Our search strategy was intentionally broad to return a wide range of psychological and social interventions aimed at violence reduction in any setting. It focused on distinct interventions rather than on holistic service models where specific elements responsible for therapeutic change would be difficult to isolate. Emergency management strategies for violence designed to reduce immediate risk (seclusion, restraint) were not included.

In forensic psychiatry patients there is considerable overlap between psychosis and PD, with dual diagnosis being the rule rather than the exception[22,23]. It is therefore pragmatic to extend the research question to include patients with PD, although we consider these results separately due to phenomenological differences between these groups. Dangerous and Severe Personality Disorder (DSPD) is an ill-defined psychiatric construct and was not included, although studies of patients with formal psychiatric diagnoses undergoing specific treatments within a DSPD environment are included.

We were interested in outcomes relating to violence within this population, and sought to include studies which measures changes in acts of verbal or physical aggression, hostile attitudes and rates of violent recidivism. Sexual violence was excluded as the determinants for this kind of violence were thought to differ from that of physical violence. We anticipated some variability in the quality of violence assessments, from objective records of violent incidents to self-report measures of violent attitudes, but elected to include all quantitative measures which could then be appraised in analysis. Studies that used anger as the sole outcome measure were excluded as anger is deemed a risk factor for (but not a marker of) violence[24]. Studies that solely investigated symptomatic changes of mental illness consequent to an intervention were excluded, as were those which used general (non-violent) recidivism as outcome.

After scoping the literature, it was apparent that very few RCTs would be returned by our search. We therefore elected to include study designs lower on the hierarchy of evidence, but included studies were required to have a control group to mitigate against the most conspicuous of confounding factors. Outcome measures were expected to be diverse, and so a narrative synthesis rather than meta-analysis was conducted.

2.4 Information sources and search strategy

We used three search strategies to identify relevant studies: electronic database searching, manual searching and expert opinion.

Electronic database searching

Titles and abstracts were identified using a web-based search of the following medical and legal databases: *MEDLINE*, *EMBASE*, *PsycINFO*, *Applied Social Sciences Index and Abstracts (ASSIA)*, *HeinOnline*. We searched in the English language only and used the following terms identified from the title or abstract:

intervention* OR therap* OR psychotherap* OR psychological OR “CBT” OR manag* OR “reasoning and rehabilitation” OR “R&R” or rehab* OR restorative OR “outpatient commitment” OR involuntary OR disposal OR treatment OR psychoeducation OR counsel*

AND

violen* OR offen* OR assault OR aggressi* OR hostile* OR homicide OR recidivis* OR crim*

AND

psychosis OR psychotic OR schizo* OR “mentally disordered offender” OR “mentally disordered offenders” OR MDO or “severe mental illness” OR SMI OR bipolar OR “personality disorder” OR “personality disordered”

The search was adapted as required to suit the individual databases.

The lead author (JR) screened the returned titles and abstracts to remove duplicates and identify articles for full text retrieval. All of the titles returned by the database search (excluding duplicated) were reviewed by a co-author (GL or VF) to ensure inter-researcher consistency of the selection. Quality and eligibility of the articles selected for full text retrieval were assessed independently between these authors and the final included articles were shortlisted. There was no conflict of opinion between authors with regards to article inclusion.

The electronic database search was completed on 9th July 2015.

Manual Search

JR completed a manual search of seven psychiatric journals that were deemed to be the most relevant to the topic by the authors, identifying publications from January 2004 until June 2015. Additionally, JR manually searched the references of all journals included in the final review for further relevant studies.

2.5 Assessment of risk of bias in individual studies and synthesis of results

JR performed a quality appraisal of articles selected for inclusion using the framework provided by the Cochrane Collaboration’s Tool for Assessing Risk of Bias[25] and completed data extraction. Co-author (ML) duplicated data extraction for a proportion of the included articles. Where there was disagreement, a third author would have acted as arbitrator but no disagreement occurred. This information was then used to direct and refine the evidence synthesis narratively. Results were analysed according to type of intervention, with further consideration given to diagnosis of subjects and the duration of follow-up.

3 RESULTS

3.1 Study selection and characteristics

Figure 1 shows the PRISMA flowchart of the review process. The database search returned 15610 articles of which 6595 were excluded as duplicates. 9032 articles were screened for eligibility, of which 85 were selected for full text retrieval. 64 of these were excluded leaving 21 studies

shortlisted for inclusion. A further 2 studies were selected after searching the references of these included articles.

The characteristics of the 23 included articles are outlined in Table 1 and risk of bias assessment is presented in Table 2.

Our review was designed to include specific interventions rather than service models as a whole. This required the exclusion of some integrated approaches to treatment from analysis, notably Secure Hospitals, the DSPD programme, the Dutch TBS system, Therapeutic Communities, Assertive Community Treatment (ACT/AOT) and Involuntary Outpatient Commitment.

The majority of included studies were described as pilot studies, adopted a quasi-experimental design and had methodological limitations including selection bias as a result of a lack of randomisation, small sample size, large drop-out rates and questionable choice of control group. Due to the overt nature of the interventions, it was not feasible to blind the subjects in any of the studies although blinding of assessors was possible. Many studies used self-report measures rather than objective outcomes increasing likelihood of desirability bias. Populations were diverse although the majority came from a setting of MDOs, and outcome measures varied meaning that narrative synthesis was employed as anticipated.

It is acknowledged that many of these studies found significance for cognitive outcomes relating to problem-solving ability, emotional stability, impulsivity and anger. These outcomes were not included as they do not directly measure violence, although theoretical associations with violence are recognised in some cases.

Results of individual studies grouped by intervention type

3.2 Cognitive Behaviour Therapy for Psychosis

A single blind RCT of CBT for psychosis versus Social Activation Therapy (SAT) was completed amongst patients with active psychosis and a history of violence, using objective outcome measures[26]. The intervention included a module directed at reducing anger linked to aggression and violence. The selection of the SAT group as control is an interesting element of the design as this neutralises the potentially confounding elements of the one-to-one therapist contact received in CBT. There were significantly fewer incidents of physical/ verbal aggression in the treatment group compared with the control group during treatment. Six months after treatment completion there were still fewer incidents in the treatment group but the difference was no longer statistically significant. However, on incidents of physical aggression alone there were improvements in the treatment group compared with control at follow up. Rates of verbal aggression did not differ significantly between groups. The authors of this study acknowledge that it may have been underpowered and their data suggests a trend towards stronger treatment effects.

A pilot study of a group CBT program for chronic psychosis within a male forensic hospital followed a cohort of program completers matched against other psychotic inpatients[27]. Sample size was small and attrition rate high, and the control group differed from treatment group on several important demographic domains. Violence outcomes were measured via subscales of the MI Observation Scale pertaining to antisocial behaviour (ASOC) and negative coping strategies (COPN), the latter of which includes (but is not limited to) verbal and physical aggression. Significant

improvements were found on COPN but not ASOC at treatment completion but methodological limitations, including baseline differences between groups and large drop-out rates, prevent firm conclusions being drawn from this study.

3.3 Cognitive Behaviour Therapy

An RCT of a CBT programme designed for treatment of Antisocial Personality Disorder (ASPD) is described in a male community population with a history of violence, using self-report measures of violence outcomes[28]. Numbers were small and whilst twelve month follow-up was impressive, many of the treatment group attended a low proportion of sessions. There were no significant differences between the groups, yet rates of verbal and physical aggression dropped significantly and comparatively in both groups over the course of the 12 months. This may indicate a therapeutic effect of Treatment As Usual (TAU) although this was not analysed. A non-significant trend towards reduced problematic drinking at follow up in the treatment group was conspicuous, considering the association between alcohol misuse and violence in this population.

A large five-year post-discharge follow-up study of the STAIR Program (System for Treatment and Abatement of Interpersonal Risk) was completed in a MDO population[29]. Recruitment was not randomised and the mirror-image experimental design adopted does not account for the expected reduction in antisocial behaviour between subjects and 'controls' over the passage of time. Additionally, the pre-group data was gathered retrospectively and post-group was gathered prospectively, so factors relating to involvement in the study itself are not controlled for.

They found that arrest rates and length of time spent in custody were significantly reduced after treatment and this might support the use of STAIR in reducing criminal behaviour in MDOs. However these findings are only indirectly relevant to violence outcomes as only 15% of re-arrests were for potentially violent offences as oppose to 52% for petty misdemeanours.

3.4 Reasoning and Rehabilitation

Reasoning & Rehabilitation[30] is a cognitive skills programme designed to reduce recidivism in offenders, but which has been evaluated specifically for its effect in reducing violence. It has been modified for use in a population of MDOs (as R&R2MHP) and for those with Attention Deficit Hyperactivity Disorder (R&RADHD).

An RCT of unmodified R&R in MDOs across six British Medium Secure (MSU) hospitals found that subjects receiving treatment engaged in fewer acts of violence than controls, but this suffered from large drop-out rates and did not reach statistical significance[31,32]. At twelve months post-completion of treatment there were no discernible differences between the groups in acts of violence or in pro-violent attitudes, yet incidents of verbal aggression were significantly reduced in the treatment group both during treatment and twelve months after completion. Psychopathy was a strong predictor of non-completion and baseline rates of aggression and violence were not reported. It may therefore be that program completers were by nature less likely to engage in verbal or physical aggression regardless of intervention. Post-hoc analysis of treatment completers versus TAU are reported but have methodological limitations. Likewise, a non-randomised quasi-experimental pilot study found no significant improvement in dissocial attitudes after completion of R&R for MDOs in an MSU setting[33].

The evidence for R&R2MHP consists of 3 nonrandomised, controlled cohort studies of male forensic patients across Low Secure (LSU), MSU and High Secure (HSU) settings and includes objective measures of antisocial behaviour[34,35,36]. Of note, drop-out rates were consistently low for this shortened form of treatment, suggesting tolerability in a forensic population. Whilst there were limitations in the comparability of control groups in terms of environment and baseline measures across these studies, there were consistent findings of improvements in attitudes pertaining to violence at treatment completion, sustained at three month follow up, and in objective measures of violent behaviour at treatment completion. In HSU settings, post-treatment worsening of violent attitudes in the control group seems more likely to account for the discrepancy between groups at the end of treatment than the effect of the intervention, although small improvements were reported for the treatment group.

Additionally, a further non-randomised waiting-list controlled trial investigated the use of R&R2MHP in female violent offenders with SMI across six secure units, excluding those who posed an acute risk of violence[37]. 16/18 subjects completed over 80% of the sessions, implying the course is tolerable within this population. However effectiveness for violence reduction was not shown, with no clinical effect of the intervention on outcomes of violent attitudes or in observed disruptive behaviour.

The authors highlight a high rate of refusal to participate in research from those completing the treatment, resulting in the study being underpowered. They also comment that the scales used to measure attitudes towards violence have mostly been evaluated within a male population, and as aggression tends to be more relational and covert in women than men, they may not be as sensitive to constructs of female violence.

The application of R&RADHD was considered in a small population of male HSU patients with a primary diagnosis of severe PD on the premise that many of the deficits that affect patients with ADHD are also seen in dissocial and borderline PD[38]. Sample size was small and there were important pre-treatment differences between groups on some measures of violence attitudes. Therefore, significant post-treatment improvements in a single domain on the Maudsley Violence Questionnaire must be treated cautiously, yet a completion rate of 75% implies tolerance of the intervention in this population.

3.5 Dialectic Behaviour Therapy (DBT)

Two eligible studies examined the use of DBT in violence reduction amongst personality disordered offenders.

A small sample of eight male HSU patients partook in an unblinded, non-randomised, controlled study[39]. Half had committed sexually violent index offences. Frequency of non-sexual violent behaviours reduced comparably in both groups. Severity of violent acts improved to a greater extent in the DBT group but pre-treatment differences in the groups compromise the ability to attribute the effect to the treatment. Self-report measures of hostility improved during but not after treatment, yet improvements were found again at 6 month follow up, whereas no improvements were seen in the TAU group at any stage. This unusual pattern of treatment improvements has been replicated in other DBT studies and is thought to reflect anxiety at treatment removal. Drop-out rates for this intense form of therapy were very low and this may be considered a significant finding.

A DBT-based group programme was evaluated in a group of female MSU patients, most of whom had a diagnosis of PD[40]. Completers had significantly fewer objectively measured incidents of physical aggression against people and scored lower on self-report measures of hostility compared with non-completers at 3 month follow up. There were no differences in verbal aggression between groups. Pre-treatment disparity between groups on outcome measures reflect inadequacies of the choice of comparator group and it is not possible to comment on the impact of treatment itself over the differing populations. In contrast to the previous study, 35% of recruited subjects dropped out of treatment.

3.6 Enhanced Thinking Skills (ETS)

ETS is designed to reduce recidivism in offending populations. Nevertheless, we found two eligible trials of group ETS programs within an MDO population with mixed PD/ psychotic diagnosis[41] or ASPD only[42]. They report on improvements in subjective measures of dissocial thinking styles and an increased likelihood for the treatment group to select less aggressive solutions to ambiguous hypothetical scenarios over the short-term. The evidence is more convincing in the male ASPD population but this remains a quasi-experimental design of a single location. Robust evidence for efficacy within a MDO population is lacking and no evidence was found for medium to long-term benefits. Objective data on violent behaviour would be welcomed to increase the evidence base for this intervention.

3.7 Anger/ Aggression Focussed Therapy

Whilst anger management groups have been appraised in a criminal justice setting, we found only two nonrandomised studies within a mental health population.

A trial of Aggression Control Therapy (ACT) was described in male forensic patients with a history of ASPD with or without SMI[43]. This study suffers from high attrition rates while control groups are mostly ignored in favour of pre-/post- treatment comparisons for the treatment group. Sampling bias is likely and some of the outcome measures had not been validated. The study concludes significant reductions of self-reported aggressive attitudes and behaviours at treatment completion, with therapy being more beneficial for subjects with low psychopathy scores. However, these conclusions are not based on comparisons with the control groups and so treatment effects cannot be reliably attributed to the intervention itself.

A further study reported on a cognitive behavioural anger management group adapted for use in a male HSU setting[44], selecting patients whose violent behaviour was deemed to derive from anger (rather than psychotic beliefs). Non completers had higher incident rates of physical aggression and self harm in the 4-6 months prior to starting the group than completers, and higher incident rates in the period after group completion. The majority of non-completers had a primary diagnosis of a psychotic disorder, whereas only 12.5% had a primary diagnosis of PD.

Rates of verbal aggression appeared to increase immediately after completion of the group but reduced after 4-9 months although not to below baseline levels. A trend towards reduced physical aggression rates after group completion was sustained for the full 9 month follow up, but significance data was not published and the paper reports a lack of statistical significance. Rates of self harm and physical aggression were low at all times in both treatment and control groups.

3.8 Schema Therapy (ST)

We found two small RCTs of ST applied to male forensic inpatients with a diagnosis of PD. Tarrier *et al*[45] suffers from being small, having a high attrition rate and of the control group receiving additional treatment, and has been criticised for the quality of therapy delivered[46]. Over a broad range of outcomes there were no differences in pro-violent attitudes between groups. Frequency of aggression dropped consistently in all subjects but with an apparent spike in aggression after six months in the treatment group.

Bernstein *et al*[46] report on the first cohort of a larger study. Final outcomes for the complete group, including three year follow up, are due by 2018. Outcome measures of violence risk via the HCR-20 are recorded alongside leave status as a proxy measure of risk. Treatment subjects HCR-20 scores improved at a faster rate than controls and they achieved leave on average 4 months earlier than those in the TAU group, but neither finding was statistically significant. This lack of significance may be mediated by a larger rate of diagnosed psychopathy in the treatment group and the lack of power in the experimental design.

3.9 Animal Assisted Therapy

A recently published RCT of animal-assisted therapy concluded efficacy for equine-assisted therapy in reducing incidents of aggression in patients with chronic SMI and a recent HoV[47].

It is argued that interaction with physically imposing yet placid animals such as trained horses can encourage the patient to model nonviolent behavioural strategies. The intervention involved group sessions, consisting of scripted and increasingly complex interactions between the patients, animals and therapists. Equine assisted therapy (EAP) was compared with canine assisted therapy (CAP), using enhanced social skills therapy (SAP) as an active control and TAU as a passive control.

Animal assisted therapy was reportedly well tolerated by the patient group although attendance was influenced by weather conditions. Attendance at SAP was worse than that for AAP. Baseline incidents of aggression were higher in the EAP than the other groups, while overall baseline rates for violence and numbers in each group was small.

Three month follow up results show that incidents of violence and scores on aggression scales (OAS) actually increased in all groups except the EAP, where there was a marked decline in incidents and OAS scores. Reductions in violence were specific findings, and there was no associated reduction in psychiatric symptoms.

3.10 Supported Housing

A group of personality disordered men received into a community DSPD programme were followed up in a study in which some were allocated to supported housing[48]. This allocation was not randomised but based on certain criteria such as motivation or inability to live independently, and is subject to confounding. Absolute offending rates were low (10%) and comorbid substance misuse high. At twelve months significantly fewer of the intervention group had reoffended compared with controls, however the rates of violent offending between groups were not statistically disparate. Low base rates for violent offending limit this study's power to detect significance.

3.11 Structured Risk Assessment

A single study considered the role of risk assessment in violence outcomes[49]. They performed an RCT of shared care planning informed by structured risk assessment (START) in a forensic out-patient setting, with re-offending as an outcome measure. Control group received TAU. There was a large drop-out rate and a third of the intervention group did not receive the intervention so it is unsurprising that no significant differences were found between groups for violent recidivism or threatened aggression at follow-up (mean of 16.2 months) although a general trend of improved outcomes was found in both groups. This lack of significance still held after completion of “as treated” analysis.

4 DISCUSSION

Good quality, methodologically sound experimental design is difficult to achieve when conducting research in this area. Most of the included studies are quasi-experimental in design, lacking in randomisation or blinding, but they are still able to inform us about trends in the data, and areas where an evidence base is assembling.

4.1 Summary of evidence

Within a male MDO population, some evidence exists for short/ medium-term improvements in physical aggression after CBT for psychosis and R&R2MHP, for improvements in verbal aggression after unmodified R&R or CBT for psychosis, and for short-term reductions in violent attitudes after R&R2MHP. One RCT found evidence for reduced aggression during and after CBT for psychosis in male psychotic patients with a history of violence.

In violent personality disordered men, engagement in CBT appears beneficial in reducing verbal and physical aggression over 12 months, possibly moderated by a reduction in problematic alcohol use. Evidence was also found for R&R2ADHD in short-term reduction of violence outcomes amongst male MDOs. Tentative evidence was found for ETS in reducing antisocial attitudes and for DBT in reducing violent acts and improved self-report measures of hostility.

Only two studies were found that looked at an exclusively female population. Neither present convincing evidence for the effectiveness of intervention (R&R2MHP/ DBT).

Across the population studied, evidence base for anger and aggression focussed therapy is currently lacking. Nor is there yet evidence to support the role of ST, supported housing or structured risk assessment in reduction of violence outcomes. EAP may reduce violence in chronically unwell psychiatric patients but access to trained horses is not feasible in most units.

Most of these studies measure only short-term outcomes. The longer-term literature tends to use recidivism as an outcome measure which was often not relevant to this study. We can conclude a dearth of evidence base for these treatments in the longer-term.

The modified forms of R&R have impressive completion rates in forensic settings approaching 80%, although selection bias may have influenced retention within treatment. Attrition rates are high for most other included psychological interventions. Non-completion is predicted by psychopathy and associated with worse outcomes[50], so psychological treatment could cause iatrogenic harm if prescribed carelessly. Tolerability of psychological interventions is an important consideration in a personality disordered population and may be grounds for feasible research in the future.

We are unable to identify any inconsistencies in the results that would not be best accounted for by the variable methodological quality and quasi-experimental approach of the majority of the included studies.

In the process of our search, we uncovered and excluded some case studies which highlighted other potential interventions. We would be interested to hear of good quality, long-term controlled studies of Acceptance and Commitment Therapy, Mindfulness, The Chromis Violence Reduction Program, Systems Training for Emotional Predictability and Problem Solving (STEPPS) and individual

or group psychotherapy in this context. No relevant studies of interventions targeting substance misuse were found.

4.2 Strengths and limitations

We believe this to be the first review to address the question of non-pharmacological means to reduce violence in a population with SMI or PD. The selection of studies allows us to comment on the potential effectiveness of specific treatment approaches within a therapeutic package which would be lost in the analysis of integrated services. We completed a thorough search of the literature since 1980 with strict exclusion criteria of subjects to improve the specificity of our results to a psychiatric population. Inter-rater reliability was consistent with no requirement for arbitration regarding inclusion of articles.

4.3 Limitations of the literature

Violence is a challenging construct to measure as no standard definition exists that is commonly used in research. This review used a range of objective and subjective measures which may be subject to differing biases including desirability and reporting bias. Patient attitudes were included as outcome measures although these are likely to be less reliable measures than quantifiable rates of violent incidents, which themselves may be susceptible to professional underreporting of incidents[51]. Base rate of violence in most of the included studies was low and this may have influence in the significance of the findings.

Methodological design was mostly restricted to quasi-experimental studies with high risk of bias and confounding. Some reported relevant baseline differences between groups but many could not account for factors such as prescribed medication, substance misuse or psychopathy between groups. Publication bias was not formally examined although we did include a number of studies that concluded negative results.

Delivery of psychological interventions may lack consistency between therapists and between studies. Nominally similar interventions were delivered in diverse fashions between studies, with variations in both the quality and the frequency of sessions. Some attempted to ensure a consistent quality between therapists through objective measures, but this could not ensure between-study consistency.

Our studies were of heterogeneous populations with diverse outcome measures and as such meta-analysis would not be informative. Knowledge of a forensic mental health population suggests that a majority of the subjects would have had a substance misuse diagnosis as a comorbidity. Substance misuse is known to heavily weight the risk of violence amongst a population with mental illness or personality disorder[52], yet this confounder could not be adequately addressed in the literature. It could be suggested that active substance misuse was less likely to have been an everyday challenge amongst inpatients in a secure hospital than those in the community, but a number of these studies were of community patients for whom ongoing substance misuse could not be controlled for.

Not all studies of PD subjects paid specific attention to the diagnosis of psychopathy, which may be considered a subset of treatment-resistant patients likely to skew the results in favour of poorer outcomes. Many underpowered studies could only report on trends towards treatment effects where larger studies may have found stronger evidence.

The authors were disappointed not to be able to include articles pertaining to court diversion schemes. A systematic review of court diversion[53] is relevant accompaniment to this topic. Likewise, no data was found on the Violence Offender Treatment Programme (VOTP). Interventions concerning substance misuse were absent from our results, although this is a well-known dynamic risk factor for violence in a SMI/PD population.

We chose to exclude Therapeutic Communities and ACT from this review but as such it will need to be considered alongside other literature on the topic. Wilson *et al*[54] assert that the social support network received in such holistic interventions is the truly beneficial ingredient in offender rehabilitation leading to improved quality of life and reduced recidivism, rather than any specific component of intervention.

However, two large multi-centre RCTs of ACT against TAU for patients with psychosis concluded no significant reduction in violent acts over 2-5 year follow-up[55,56]. These RCTs were not of offender populations, so it could be argued that the potential social cohesion received from integrated treatment packages may have particular relevance in offender rehabilitation. Our review is unable to inform on this matter.

4.4 Implications and Conclusion

The dearth of high quality evidence for specific interventions in this field has practical and financial implications for the rehabilitation of MDOs and psychiatric patients with a history of violence, and more research is urgently needed. The continued detention of violent MDOs in an environment where rehabilitation for violence lacks robust evidence base requires justification on both ethical and financial grounds.

Within a male SMI population, CBT and modified R&R have shown the most promise and may be the most fruitful targets for further interventions. There is less clarity within the male PD population. In both cases, serious consideration needs to be given to drop-out rates as failure to complete treatment is associated with worse outcomes in an MDO population. The data fails to inform on the effectiveness of non-pharmacological treatment for women with SMI/ PD and a history of violence.

Some studies reported reductions in violence within TAU control groups that mirrored the reduction in the intervention groups. This may reflect a therapeutic effect of the environment in which the studies were conducted and suggest that the overall quality of integrated care being received may be more significant a factor than the specific intervention on offer.

In reality, the treatment of this complex group extends beyond the modification of violent behaviour and is likely to require multiple strands, addressing a range of psychological, psychiatric, interpersonal and social factors. It is plausible to suppose that a PD population will benefit best from moderating antisocial attitudes and traits whilst an SMI population may focus on a reduction of acute symptomatology followed by holistic social support and an assessment of pro-violence attitudes. Both populations could be expected to benefit from a reduction in the dynamic risk factors associated with violence such as homelessness, poverty and substance misuse.

High quality, well powered RCTs, with medium to long-term follow up are required before strong evidence can be asserted for any of the interventions discussed in this paper. The inclusion of some well designed RCTs indicates that such an approach is possible in this context. A further review,

looking at the outcomes of integrated services such as secure hospitals, TCs and AORTs, may further inform policy and incorporate an element of social cohesion that is not addressed here.

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Figure 1

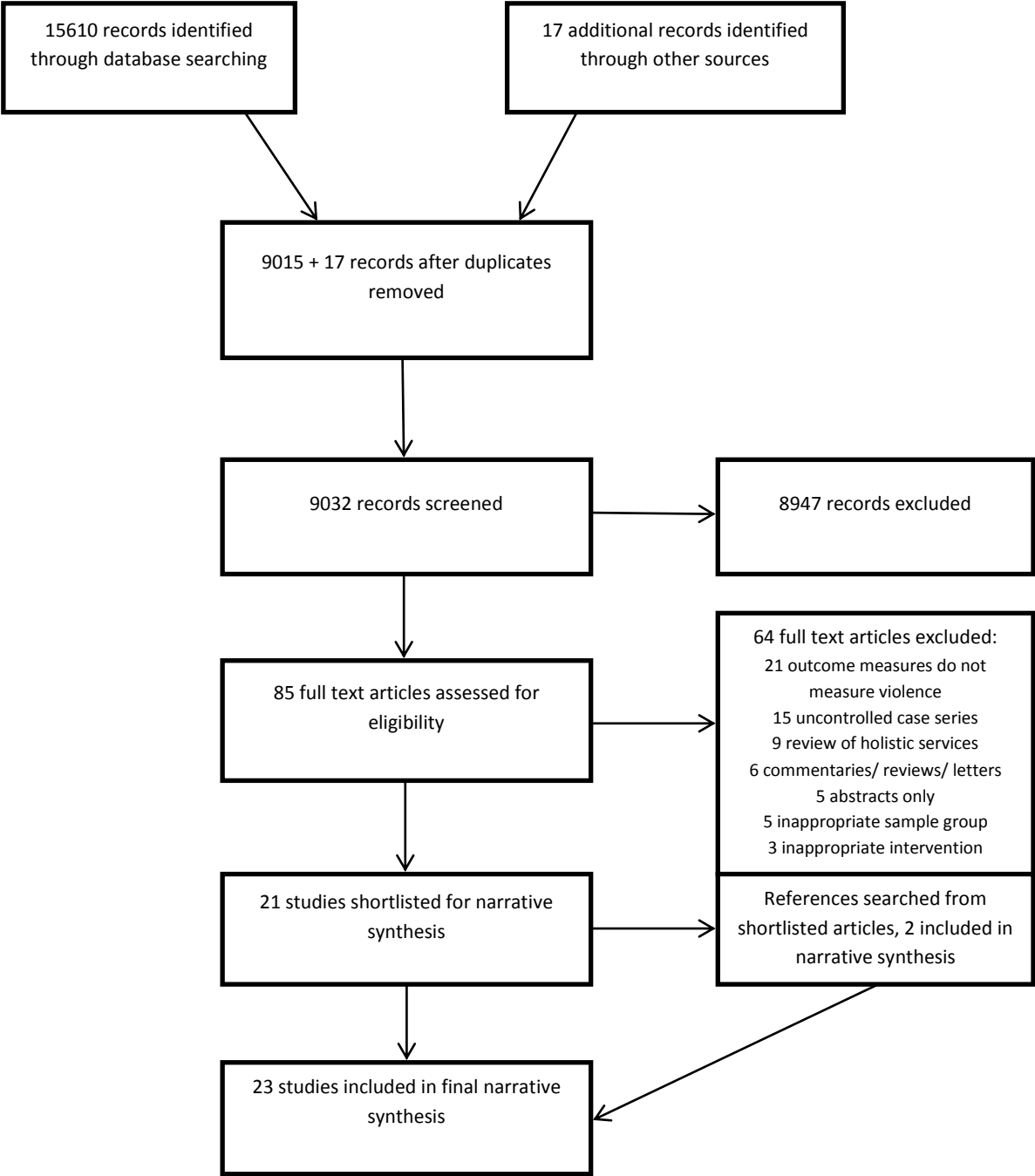


Fig 1. PRISMA flowchart of review process

Table 1

AUTHOR	INTERVENTION	POPULATION	# RECRUITED	DESIGN	RELEVANT OUTCOME MEASURES	OUTCOME TIMING	WEAKNESSES
Haddock et al 2009 (26)	CBT for psychosis 25 sessions over 6 months	Inpatients and Outpatients 85% male Psychotic disorder + HoV	38 subjects 39 SAT controls 11% drop out rate	RCT ITT analysis	Violence incidents (objective)	During treatment, treatment completion, 6 months after completion	Disparate sample group Single blind design. Allocation of drop-outs not specified. Underpowered.
Hornsveld et al 2005 (27)	CBT for psychosis Mixed individual and group over 12 months	Forensic Inpatients Male Chronic psychosis	16 subjects 16 TAU controls	Non randomised controlled trial PPA	MIOS	Before and after treatment	Not randomised. Baseline differences in control group (demographic/violence). Large drop-out rate, reasons not explicit. Underpowered.
Davidson et al 2009 (28)	Individual CBT 15 sessions over 6 months or 30 sessions over 12 months	Community Male ASPD + HoV	20 subjects 21 TAU controls	RCT ITT analysis	MCVSI Violence incidents (objective)	During treatment and at treatment completion	Poor engagement in treatment. Desirability bias. Underpowered. No active control treatment
Yates et al 2010 (29)	STAIR Inpatient 72 sessions	Inpatients 90% male MDO (SMI)	145 subjects Mirror-image control	Prospective cohort with retrospective mirror image control	Re-arrests	Up to 5 year follow up	Not randomised. Mirror-image control design. Variable follow-up duration. Arrests predominantly not violent. Bonferroni correction increases risk of Type II error.
Cullen et al 2012 (31,32)	R&R 36 sessions	MSU Male SMI + HoV	21 subjects 40 TAU controls	RCT ITT analysis	CRIME-PICS II NAS Physical aggression (objective) Verbal aggression (objective)	During treatment, 12 month post treatment	Large drop out rate. Includes post-hoc analysis. Desirability bias. Low violence base rates.
Clarke et al 2010 (33)	R&R 36 sessions	MSU Male SMI + HoV	15 subjects 17 TAU controls	WL Control PPA	CRIME-PICS II	Treatment completion	Not randomised. Non-equivalent groups (different units). Desirability bias. Underpowered.
Young et al 2010 (34)	R&R2M 16 sessions	MSU + HSU Male	22 subjects 12 WL control	WL control PPA	MVQ DBSP	Treatment completion	Not randomised. Non-equivalent groups (HSU v

		SMI + HoV					MSU). Large drop out rate (HSU > MSU) Desirability bias. Underpowered
Rees-Jones et al 2012 (35)	R&R2M 16 sessions	MSU + LSU Male SMI + HoV	52 subjects 54 WL control	WL Control ITT analysis	MVQ DBSP NAS	Treatment completion, 3 month post-treatment	Not randomised. Non-equivalent groups (LSU v MSU). Desirability bias. Data subject to floor effect.
Yip et al 2013 (36)	R&R2M 16 sessions	HSU Male SMI + HoV	24 subjects 29 controls	Non-randomised controlled trial ITT analysis	MVQ DBSP NAS	Treatment completion	Not randomised. Worsening of outcomes in control group. Baseline differences between groups (outcome measures). Desirability bias. Underpowered.
Jotangia et al 2015 (37)	R&R2M 16 sessions	MSU + LSU Female SMI + HoV	16 subjects 20 TAU controls	WL Control ITT analysis Ad hoc PPA	MVQ DBSP NAS	Treatment completion, 3 month post-treatment	Not randomised. Underpowered Construct validity (Measures not validated for female population). Selection bias Missing data
Young et al 2013 (38)	R&R2ADHD 15 sessions	HSU Male Severe PD + HoV	12 subjects 15 controls	WL Control ITT analysis	MVQ NAS	Treatment completion	Not randomised. Baseline differences between groups (violent attitudes). Desirability bias. Underpowered.
Evershed et al 2003 (39)	DBT One group and one individual session per week over 18 months	HSU Male BPD	8 subjects 9 TAU controls	Non randomised controlled trial PPA	Violence incidents (objective) BDHI-D	During treatment, treatment completion. 6 month post treatment completion	Not randomised. Baseline differences between groups (clinical). Desirability bias. Non-concurrent TAU group. Reasons for drop-outs not explicit. Underpowered.
Long et al 2011 (40)	'Dealing with Feelings'. Mixed individual and	MSU Female 70% PD	29 subjects 15 non completers	Pre-post test design PPA with treatment non-	Violence incidents (OAS) BPRS-hostility	3 months post treatment completion	Not randomised. Not true control Baseline

	group DBT. 17 group sessions.	30% SMI HoV		completers used as comparison group			differences between groups (demographic/ violence/ clinical) . Underpowered.
Tapp et al 2009 (41)	ETS 20 sessions	HSU Male SMI or Severe PD or DDx	62 subjects 21 non-completers	Pre-post test design PPA with treatment non-completers used as comparison group	PICTS SPSI	Treatment completion	Not randomised. Not true control. Missing outcome data. Desirability bias. ITT not adopted
Doyle et al 2013 (42)	ETS 20 sessions	Prisoners Male ASPD	55 subjects 50 WL controls	WL Control LOCF	APQ SPSI NAS	Treatment completion	Not randomised. Single blind. Desirability bias. Psychopathy not addressed.
Hornsveld et al 2008 (43)	ACT Weekly sessions for 15 weeks, 3 follow up sessions at five weekly intervals	Forensic inpatients and outpatients Male ASPD +HoV +/- SMI	Data is unclear	Non randomised controlled trial PPA	ATV AVL NAS OSAB	During treatment and at completion	Not randomised. Control groups inappropriate and ignored in analysis. High drop out in outpatient group Unclear data relating to subject allocation and drop-out. Desirability bias. Unvalidated outcome measures.
Wilson et al 2013 (44)	Modified anger management group (CBT) 20 weekly sessions	HSU Male	48 subjects 64 WL controls	WL Control PPA	Incidents of aggression (objective)	1-3, 4-6 and 7-9 months pre-treatment. 1-3, 4-6 and 7-9 months post treatment	Not randomised. Missing incident data. Low incident base rate. Violence data skewed by individual patients Selection bias.
Tarrier et al 2010 (45)	ST weekly for up to 2 years	HSU Male PD	25 subjects 24 controls	RCT ITT analysis	APQ HCR-20 MOAS VRS IBRS	During treatment, treatment completion, 36 months	Not true control. Large drop-out rate. Underpowered. Questionable standard of therapy.
Bernstein et al 2012 (46)	ST Twice weekly, max 3 years	Forensic Inpatients Male PD	16 subjects 14 TAU controls	RCT PPA	HCR-20 START Supervised/ unsupervised leave	During treatment and at treatment completion	Selective outcome reporting. ITT not adopted. Baseline differences between groups (psychopathy).

							Underpowered.
Nurenberg et al 2015 (47)	AAT 10 weekly group sessions	Chronic SMI 63% male Recent HoV	24 EAP 25 CAP 23 Active control 18 TAU control	RCT PPA	Violence incidents (objective) OAS	2 months before treatment, 3 months after starting treatment	Method of randomisation not specified. Lack of blinding. Low baseline violence rates. Likely disheartening effect of being in control group.
Bruce et al 2014 (48)	Supported Housing	Outpatients Male DSPD	62 subjects 45 TAU controls	Retrospective cross-sectional cohort study with TAU control	Violent offending rates	12 months	Not randomised. Low violence base rates. Low violence incidence rates. Underpowered.
Troquette et al 2013 (49)	Structured Risk Assessment and Shared Care Planning	Outpatients under forensic case managers Patient demographics and diagnoses not specified	632 subjects within 58 clusters	Cluster RCT ITT	Violence incidents	Variable follow up	Large proportion of treatment group did not receive intervention. Large drop out rate. More drop outs in control group.

INTERVENTIONS

AAT= Animal Assisted Therapy ; ACT= Aggression Control Therapy; CBT= Cognitive Behavioural Therapy; DBT= Dialectical Behaviour Therapy; ETS= Enhanced Thinking Skills; R&R= Reasoning and Rehabilitation; R&R2M= R&R Mental Health Program; ST= Schema Therapy; STAIR= Service for Treatment and Abatement of Interpersonal Risk

POPULATION

ASPD= AntiSocial Personality Disorder; DDx= Dual Diagnosis; DSPD= Dangerous and Severe Personality Disorder programme; HoV= History of Violence; HSU= High Secure Unit; LSU= Low Secure Unit; MDO= Mentally Disordered Offenders; MSU= Medium Secure Unit; PD= Personality Disorder; SMI= Severe Mental Illness

RECRUITED/ DESIGN

ITT= Intention To Treat; LOCF= last observation carried forward; PPA= per protocol analysis; RCT= randomised controlled trial; SAT= Social Activity Therapy; TAU= Treatment As Usual; WL= Waiting List

OUTCOME MEASURES

APQ= Antisocial Personality Questionnaire; ATV= Attributie Vragenlijst; AVL= Agressie Vragenlijst; BDHI-D= Buss-Durkee Hostility Inventory; BPRS= Brief Psychiatric Rating Scale; DBSP= Disruptive Behaviour and Social Problem Scale; HCR-20= Historic Clinical Risk Management-20; IBRS= Institutional Behaviour Rating Scale; MCVSI= Macarthur Community Violence Screening Instrument; MIOS= Meijers Institute Observation Scale; MOAS= Modified Overt Aggression Scale; MVQ= Maudsley Violence Questionnaire; NAS= Novaco Anger Scale; OAS= Overt Aggression Scale; OSAB= Observation Scale for Aggressive Behaviour; PICTS= Psychological Inventory of Criminal Thinking Styles; SPSI= Social Problem-Solving Inventory; START= short-term assessment of risk and treatability; VRS= Violence Risk Scale

WEAKNESSES

CI= Confidence Intervals

Table 1. Characteristics of included articles

Table 2

PAPER	SEQUENCE GENERATION	ALLOCATION CONCEALMENT	BLINDING
HADDOCK 2009	LOW	LOW	HIGH
HORNSVELD 2005	HIGH	HIGH	HIGH
DAVIDSON 2009	LOW	LOW	HIGH
YATES 2010	HIGH	HIGH	HIGH
CULLEN 2012	LOW	LOW	HIGH
CLARKE 2010	HIGH	HIGH	HIGH
YOUNG 2010	HIGH	HIGH	HIGH
REES-JONES 2012	HIGH	HIGH	HIGH
YIP 2013	HIGH	HIGH	HIGH
JOTANGIA 2015	HIGH	HIGH	HIGH
YOUNG 2013	HIGH	HIGH	HIGH
EVERSHED 2003	HIGH	HIGH	HIGH
LONG 2011	HIGH	HIGH	HIGH
TAPP 2009	HIGH	HIGH	HIGH
DOYLE 2013	HIGH	HIGH	HIGH
HORNSVELD 2008	HIGH	HIGH	HIGH
WILSON 2013	HIGH	HIGH	HIGH
TARRIER 2010	LOW	LOW	HIGH
BERNSTEIN 2012	LOW	LOW	HIGH
NUREMBERG 2015	UNCLEAR	UNCLEAR	HIGH
BRUCE 2014	HIGH	HIGH	HIGH
TROQUETTE 2013	LOW	LOW	HIGH

Table 2 (continued)

PAPER	INCOMPLETE OUTCOME DATA	SELECTIVE OUTCOME REPORTING	OTHER SOURCES OF BIAS
HADDOCK 2009	UNCLEAR	LOW	HIGH
HORNSVELD 2005	HIGH	LOW	HIGH
DAVIDSON 2009	LOW	LOW	HIGH
YATES 2010	HIGH	LOW	HIGH
CULLEN 2012	LOW	HIGH	HIGH
CLARKE 2010	UNCLEAR	LOW	HIGH
YOUNG 2010	HIGH	LOW	HIGH
REES-JONES 2012	LOW	LOW	HIGH
YIP 2013	LOW	LOW	HIGH
JOTANGIA 2015	HIGH	LOW	HIGH
YOUNG 2013	LOW	LOW	HIGH
EVERSHED 2003	UNCLEAR	LOW	HIGH
LONG 2011	LOW	LOW	HIGH
TAPP 2009	HIGH	LOW	HIGH
DOYLE 2013	LOW	LOW	HIGH
HORNSVELD 2008	HIGH	LOW	HIGH
WILSON 2013	HIGH	LOW	HIGH
TARRIER 2010	HIGH	HIGH	HIGH
BERNSTEIN 2012	LOW	HIGH	HIGH
NUREMBERG 2015	LOW	LOW	HIGH
BRUCE 2014	LOW	LOW	HIGH
TROQUETTE 2013	LOW	LOW	HIGH



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	title
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	3
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	3/4
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4/5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Table 1
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	4
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	4, Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Table 1
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	5-10
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	14

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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19th January 2016

The editor
European Psychiatry

Ms. Ref. No.: EURPSY-D-15-00400

Title: Non-pharmacological interventions for reducing aggression and violence in serious mental illness: a systematic review and narrative synthesis

Professor Frangou,

I thank you for considering our review for publication, and for the positive feedback we have received.

Reviewer 1 has kindly recommended that the paper is published “as is”.

Reviewer 2 has highlighted that there are few methodologically well-designed papers included in our systematic review, which we have also commented upon in our discussion on page 11 (paragraph 1) and page 12 (paragraph 3) of the original submission.

Reviewer 2 also makes comment on our exclusion criteria, stating that the inclusion of subjects with intellectual disability would increase the value of the manuscript. We accept this point but we argue that mentally disordered offenders (MDO) with intellectual disability are a discrete subgroup of the MDO population, for whom psychological interventions would need to be substantially adjusted to be effective. This therefore becomes a different research question (looking at different interventions within a different population) and one to be addressed in a separate paper.

Reviewer 2 suggests that analysis of interventions directed at substance misuse would be informative. We did not, in fact, exclude interventions directed at addressing substance misuse and included subjects who had substance misuse as a comorbidity to a severe mental illness or personality disorder (PD), but not those with a primary diagnosis of substance misuse. Our search did not return any studies of interventions targeting substance misuse within a SMI population using outcome measures pertaining to violence and, if it had, then these would have been included. Rather like PD, substance misuse is the norm rather than the exception in a MDO population and we agree with the reviewer that it would be highly informative to consider the impact of a substance misuse intervention on violence outcomes within this population. We have clarified this matter with a concluding sentence in paragraph 4.1.

Reviewer 2 accepts that these “*comments concern the strategy of the database searching and do not diminish the value of the presented results*”. At this stage in the review process, we would be unable to expand the search to include individuals with a diagnosis of intellectual disability or a primary

diagnosis of substance misuse as this would require a significant upheaval of the paper as it is presented and delay publication to a point whereby the review may be considered 'out of date'.

Reviewer 2 makes the valid point that study-to-study consistency may be poor and that this should be highlighted in the text. We have made mention of this matter in the discussion on page 12 (paragraph 4) of the original submission.

I hope that you find our response to these generous reviews to be appropriate.

Yours

A handwritten signature in grey ink, appearing to be 'JR' or similar initials, written in a cursive style.

Dr Jeremy Rampling